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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,769	05/02/2005	Federica Damiani	P33037	6760
20462 7590 03/10/2008 SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939				
EXAMINER				
CHANG, CELIA C				
ART UNIT		PAPER NUMBER		
1625				
NOTIFICATION DATE		DELIVERY MODE		
03/10/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US\_cipkop@gsk.com

### Office Action Summary

**Application No.**

10/511,769

**Applicant(s)**

DAMIANI ET AL.

**Examiner**

Celia Chang

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's election without traverse of group I, with example 6 as the elected species in the reply filed on Dec. 7, 2007 is acknowledged.

Claim 11 and claims 1-10, 12-19 wherein X is CH<sub>2</sub> or CHR<sub>5</sub> reading on the election is prosecuted. Claims 20-21 stayed withdrawn together with the remaining subject matter of claims 1-10, 12-19 per CFR 1.142(b). Claims 20-21 stayed withdrawn as being in the nonstatutory use format and cancellation is again recommended.

2. Claims 15-17 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1-11. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Please note that the intended use does not bear weight, thus, such scope is not further limiting the base claim. Claims 15-17 are therefore the identical compounds of claims 1-11.

3. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating anxiety employing the claimed compounds, does not reasonably provide enablement for treating all CNS disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

It is recognized in the art that 5HT<sub>2C</sub> receptor antagonists have efficacy in treating anxiety (see CA 132). Receptor binding is structural sensitive which is very much like the lock and key situation wherein the key is the claimed compounds. It is well known in the art that antagonistic binding of the 5HT<sub>2C</sub> receptor results in treating depression (see Martin et al.) while antagonistic binding of 5HT<sub>2C</sub> receptor results in treating anxiety (see Bromidge et al.).

The instantly claimed compounds were tested by the method of WO94/04533 (see specification p.10) thus, having 5HT<sub>2C</sub> antagonistic activity. The specification, therefore, supports the method of treating anxiety but not all CNS disorder.

4. Claims 1-11, 15-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13, 15-19 of copending Application No. 10/518,118 in view of WO 03/57220.

The difference between the instant claims and the copending claims is the position isomerism that is the location of the substituents on the core structure. The instant claims have the YCH<sub>2</sub>DZ being located on the N-phenyl ring while the copending claims have the YCH<sub>2</sub>DZ on the C-phenyl ring. Position isomerism has long been recognized in the chemical art being structural prima facie. See *In re Dillon* 16 USPQ2d 1897, 1911; *In re Surrey* 138 USPQ 607, *Ex parte Ullyot* 103 USPQ 185. The well recognized structural prima facie obviousness being relevant to the field of 5HT<sub>2c</sub> art is further supported by the WO 03/57220 reference. WO 03/57220 is in the same field of endeavor of 5HT<sub>2c</sub> receptor active compounds. This reference provided factual evidence supporting the prima facie obviousness of position isomerism because variation of the central five member nucleus with C or N atom i.e. position isomerism of the above YCH<sub>2</sub>DZ is considered ring equivalency.

This is a provisional obviousness-type double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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5. Claim 11 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims *when the proper terminal disclaimer is filed*.

Claims 1-10 would be allowable when the non-elected invention is removed and the compounds are limited to formula I wherein X is CH<sub>2</sub> or CHR<sub>5</sub> compounds *when the proper terminal disclaimer is filed*.

The X is CH<sub>2</sub> or CHR<sub>5</sub> compounds are novel and unobvious because the claims have clearly demarcated from the closest art of record in CA120 wherein the YCH<sub>2</sub>DZ requires at least a three atom insertion between the phenyl ring and the Z moiety. No motivation in modifying the prior art aminomethyl moiety with the instant YCH<sub>2</sub>DZ moiety.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Feb. 27, 2008

/Celia Chang/  
Primary Examiner  
Art Unit 1625